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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|----------------------|----------------------|----------------------|------------------|
| 09/920,571 | 07/31/2001 | Roger S. Lasken | 17104.0001U2 | 4875 |
| 23859 7590 03/06/2007 NEEDLE & ROSENBERG, P.C. SUITE 1000 | | | EXAMINER | |
| | | | STRZELECKA, TERESA E | |
| 999 PEACHTF ATLANTA, G | | | ART UNIT | PAPER NUMBER |
| , , , , , , , , , , , , , , , , , , , | | | 1637 | |
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| SHORTENED STATUTOR | Y PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE | |
| 31 DAYS | | 03/06/2007 | PAPER | |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| | | Application No. | Applicant(s) | | | | |
|---|--|---|---|--|--|--|--|
| Office Action Summary | | 09/920,571 | LASKEN ET AL. | | | | |
| | | Examiner | Art Unit | | | | |
| | | Teresa E. Strzelecka | 1637 | | | | |
| Period fo | The MAILING DATE of this communication app or Reply | pears on the cover sheet with the | correspondence address | | | | |
| A SHO WHIC - Exter after - If NO - Failui Any r | ORTENED STATUTORY PERIOD FOR REPLY CHEVER IS LONGER, FROM THE MAILING DATE in a sions of time may be available under the provisions of 37 CFR 1.13 SIX (6) MONTHS from the mailing date of this communication. Period for reply is specified above, the maximum statutory period were to reply within the set or extended period for reply will, by statute, reply received by the Office later than three months after the mailing and patent term adjustment. See 37 CFR 1.704(b). | ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tin will apply and will expire SIX (6) MONTHS from a cause the application to become ABANDONE | N. nely filed the mailing date of this communication. ED (35 U.S.C. § 133). | | | | |
| Status | | | •• | | | | |
| 1)[X] | Responsive to communication(s) filed on 11 De | ecember 2006 | • | | | | |
| | •— | | | | | | |
| , | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is | | | | | | |
| ٥,۵ | closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. | | | | | | |
| Dispositi | on of Claims | , | | | | | |
| - | | 11.10 51 52 55 50 and 60 91 icl | are pending in the application | | | | |
| | 4) Claim(s) <u>1,5-9,14,20,22-25,27,29,35-39,41,42,44-49,51-53,55-59 and 69-84</u> is/are pending in the application. | | | | | | |
| | 5) Claim(s) is/are allowed. | | | | | | |
| • | S) Claim(s) is/are allowed. | | | | | | |
| · | | | | | | | |
| , | Claim(s) <u>See Continuation Sheet</u> are subject to | restriction and/or election requi | rement | | | | |
| * | | restriction and/or election requi | ement. | | | | |
| | on Papers | | | | | | |
| | The specification is objected to by the Examine | | | | | | |
| 10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner. | | | | | | | |
| | Applicant may not request that any objection to the | | • • | | | | |
| 11)[7] | Replacement drawing sheet(s) including the correcting the oath or declaration is objected to by the Extension is a specific to be supported to be a specific to the contract of the contract o | | , , | | | | |
| | | diffice the attached Office | Action of 10111 F 10-132, | | | | |
| | nder 35 U.S.C. § 119 | | • | | | | |
| _ | Acknowledgment is made of a claim for foreign ☐ All b) ☐ Some * c) ☐ None of: | priority under 35 U.S.C. § 119(a |)-(d) or (f). | | | | |
| | 1. Certified copies of the priority documents have been received. | | | | | | |
| | 2. Certified copies of the priority documents have been received in Application No | | | | | | |
| | 3. Copies of the certified copies of the prior | | | | | | |
| | application from the International Bureau | | · | | | | |
| * S | ee the attached detailed Office action for a list of | * ** | ed. | | | | |
| | | · | • | | | | |
| Attachment | (s) | | | | | | |
| | e of References Cited (PTO-892) | 4) Interview Summary | (PTO-413) | | | | |
| 2) 🔲 Notice | e of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Da | ate | | | | |
| | nation Disclosure Statement(s) (PTO/SB/08) No(s)/Mail Date <u>8/28/06</u> . | 5) Notice of Informal F 6) Other: | atent Application | | | | |

Continuation of Disposition of Claims: Claims subject to restriction and/or election requirement are 1,5-9,14,20,22-25,27,29,35-39,41,42,44-49,51-53,55-59 and 69-84.

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DETAILED ACTION

Election/Restrictions

1. This application contains claims directed to the following patentably distinct species:

Species of fluorescent labels

- A) the fluorescent label is a CyDye and the CyDye is Cy2 (claims 72, 73),
- B) the fluorescent label is a CyDye and the CyDye is Cy3 (claims 72, 73)
- C) the fluorescent label is a CyDye and the CyDye is Cy3.5 (claims 72, 73)
- D) the fluorescent label is a CyDye and the CyDye is Cy5.5 (claims 72, 73)
- E) the fluorescent label is fluorescein (claim 74),
- F) the fluorescent label is 5,6-carboxymethyl fluorescein (claim 74),
- G) the fluorescent label is Texas red (claim 74),
- H) the fluorescent label is nitrobenz-2-oxa-1,3-diazol-4-yl (NBD) (claim 74).
- I) the fluorescent label is coumarin (claim 74),
- J) the fluorescent label is dansyl chloride (claim 74),
- K) the fluorescent label is rhodamine (claim 74).

Species of dNTPs

- L) at least one said dNTP is a fluoresecence-labeled nucleotide (claim 75),
- M) at least one said dNTP is fluorescein- isothiocyanate-dUTP (claim 76),
- N) at least one said dNTP is Cyanine-3-dUTP (claim 76),
- O) at least one said dNTP is Cyanine-5-dUTP (claim 76),
- P) at least one said dNTP is modified (claim 77),
- Q) at least one said dNTP is modified with biotin (claim 78),
- R) at least one said dNTP is modified with a hapten (claim 78),

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- S) at least one said dNTP is a nucleotide analog (claim 79),
- T) at least one said dNTP comprises a radioactive isotope (claim 80).

Species of labeling the TS-DNA

- U) the label is incorporated into the TS-DNA during the formation of TS-DNA (claim 1, 81),
 - V) the TS-DNA is labeled with a labeled probe (claim 1, 82),
 - W) the TS-DNA is labeled with an intercalating label (claim 1, 83),
 - X) the TS-DNA is labeled by incorporation of a labeled dNTP (claim 1, 84).

The species are independent or distinct because, in the case of fluorescent labels, each has a different structure and emission characteristics; in the case of modified dNTPs, each has a different structure which leads to a differences in the final product obtained; and in the case of the labeling TS-DNA, each of the species results in the differences in method steps.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable, i.e., Applicants are required to elect one species from the set of fluorescent labels, one species from the set of modified dNTPs and one species from the set of TS-DNA labeling.

Currently, claim 1 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable

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generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

2. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teresa E. Strzelecka whose telephone number is (571) 272-0789. The examiner can normally be reached on M-F (8:30-5:30).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Teresa E Strzelecka Primary Examiner Art Unit 1637

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